UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,371	06/13/2001	Zhong-Min Wei	21829/91 (EBC-007)	4973

7590 07/01/2003

Michael L. Goldman
NIXON PEABODY LLP
Clinton Square
P.O. Box 31051
Rochester, NY 14603

EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	19

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,371	WEI ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-11,13-21,75 and 76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-11,13-21,75 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-2, 12 and 22-74 have been cancelled, claims 3-5, 7, 10-11, 13-15, 17 and 20-21 have been amended, and claims 75-76 have been added as requested in Paper No. 17, filed 9 April 2003. Claims 3-11, 13-21 and 75-76 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 3-11, 13-21 and 75-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "transgene that confers a value added transgenic trait ... does not encode a hypersensitive sensitive response elicitor protein or polypeptide" in claim 75, lines 3-5, and claim 76, lines 4-6. Thus, such a phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

4. Claims 3-11, 13-21 and 75-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the

reasons of record as set forth in the Office action mailed 7 November 2002, as applied to claims 1-21. Applicant's arguments and the Declaration of Ernest J. De Rocher, both filed 9 April 2003, have been fully considered but they are not persuasive.

Applicant summaries the Declaration, so both will be summarized here: Hypersensitive response elicitor proteins are an art-recognized class of proteins and share the unique ability to cause distinct plant responses. Gopalan et al (1996, Plant Dis. 80:604-610) teaches that the hypersensitive response results from an incompatible interaction between plant pathogens and non-host plants and this reaction is distinct from a compatible interaction. Gopalan also teaches that hypersensitive response elicitor proteins from one genus are often homologous to elicitors of a different species and genus. Bauer et al (1995, MPMI 8:484-491), Cui et al (1996, MPMI 9:565-573), Ahmad et al (1996, 8th Int'l Cong. Molec. Plant Microbe Inter.), and Preston et al (1995, MPMI 8:717-732) teach that a nucleic acid encoding a hypersensitive response elicitor protein from one bacterial species was used to isolate a nucleic acid encoding a hypersensitive response elicitor protein from the same genus. Bonas (1994, Current Topics in Microbiol. Immunol. 192:79-98), Alfano et al (1997, J. Bacteriol. 179:5655-5662), and Swanson et al (1999, Phytopath. 90:S75) teach that genes encoding hypersensitive response elicitors are arranged in gene clusters. Bogdanove et al (1996, Molec. Microbiol. 20:681-683) teach that most hypersensitive response elicitors are secreted through the type III secretion system. Bonas (*op cit*) and Wei et al (2000, MPMI 13:1251-1262) teach that the genes are regulated by environmental factors. Bonas (1994, Current Topics in Microbiol. Immunol. 192:79-98), Bonas (1994, Trends Microbiol. 2:1-2), Alfano et al, Gopalan et al, and Fan et al (WO 01/98501) teach that hypersensitive response elicitor proteins share common characteristics and structure. Wei et

al al (1996, Acta Hort. 411:223-225) Alfano et al, Strobel et al (1996, Plant J. 9:431-439) and Qui et al (US Patent 6,277,814) teach that hypersensitive response elicitors induce plant responses that include disease resistance to a broad range of pathogens and enhance plant growth. WO 02/37960 teaches that postharvest application of HrpN increased the longevity of cut roses. The Declaration presents data showing that topical application of the hypersensitive response elicitor protein from *Xanthomonas campestris* pv. *pelargonii* (HreX) induced resistance to diseases caused by other pathogens and enhanced plant growth; topical application of the hypersensitive response elicitor protein from *Pseudomonas syringae* also enhanced plant growth. Wei et al (WO 00/28055) teach that HrpN induces resistance to plant stress, and the Declaration presents data showing that topical application of HreX also induces plant stress resistance (response pg 6-8 and Declaration ¶ 5-34).

This is not found persuasive. Most of these arguments are drawn to enablement or other considerations, and will not be addressed here. That proteins have similarity of function does not provide written description of the sequence of those proteins. The claims are drawn to use hypersensitive response elicitor proteins from *Erwinia*, *Xanthomonas*, *Pseudomonas*, *Phytophthora*, and *Clavibacter* species, but the specification does not describe the sequence of hypersensitive response elicitor proteins from a representative number of those species.

Applicant urges that given that one of skill in the art would understand that the results achieved with one hypersensitive response elicitor would be expected with other members of the class, the application provides written descriptive support for the entire art-recognized class. Applicant also argues that the Office has cited no basis for suggesting that HrpN should be distinguished from other members of the class of hypersensitive response elicitor proteins

(response pg 8-9).

This is not found persuasive. The specification must describe the sequence of hypersensitive response elicitor proteins from a representative number of *Erwinia, Xanthomonas, Pseudomonas, Phytophthora*, and *Clavibacter* species for the method to have written description, but the specification does not do so. HprN is distinguished other hypersensitive response elicitor proteins because its sequence is taught in the specification.

Applicant urges that the DNA encoding a value-added trait is directed to ones harboring a value added trait, not any transgenic trait, and many such traits are described on pg 33-36 of the specification (response pg 9).

This is not found persuasive because the rejection was for a lack of written description for transgenic traits that are associated with a deleterious effect, as claimed in claim 76. The specification does not describe such DNAs.

5. Claims 3-11, 13-21 and 75-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of topical application of $harpin_{Ea}$ to transformed and non-transformed plants, does not reasonably provide enablement for a method of topical application of any hypersensitive response elicitor protein to plants comprising any transgenic trait that is associated with any deleterious effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 November 2002, as applied to claims 1-21. Applicant's arguments and the Declaration of Ernest J. De Rocher, both filed 9 April 2003, have been fully considered but they are not persuasive.

Applicant urges that for reasons noted above, results obtained from use of hypersensitive response elicitors other than $Harpin_{Ea}$ would also be expected from use of other hypersensitive response elicitors (response pg 9).

This is not found persuasive because the specification does not teach the sequence of other hypersensitive response elicitors within the full scope of the claims.

The Declaration teaches that Roundup resistant corn plants and seeds, when treated with $Harpin_{Ea}$, had higher yields than control plants. Applicant also pointers out that the Office action stated that Examples 6-8 and 10 of the specification teach other such transgenic plants (Declaration ¶35-38 and response pg 10-11).

This is not found persuasive. The rejection already stated that the specification was enabled for use of $harpin_{Ea}$. The specification does not teach plants comprising transgenic traits other than Bt that are associated with a deleterious effect. The specification does not teach which hypersensitive response elicitor proteins compensate for the deleterious trait of which transgenic trait.

The Declaration submits that Elmore et al (2001, Agronomy J. 93:408-412) teach that glyphosate-resistant soybean plants had reduced yield (Declaration ¶39).

This is not found persuasive because the instant specification fails to provide guidance for other hypersensitive response elicitor proteins or for plants comprising other transgenic traits that are associated with a deleterious effect. See also *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Applicant urges that Dong et al, cited in the prior Office action, is irrelevant because

nahG did not confer a value-added trait and the experiment was done only to inactivate salicyclic acid accumulation; infiltration with HrpN was done to study signal transduction, not to overcome a deleterious effect of the transgene. Thus, Applicant urges that Dong et al do not support the rejection (response pg 11).

This is not found persuasive. The specification does not define "value-added", but only gives examples of traits that can be value-added. Applicant provides no arguments as to why NahG is not a value-added trait as defined in the specification. Furthermore, the purpose of the experiment of Dong et al is irrelevant; Dong et al performed all the steps of the instant method; thus Dong et al is very relevant to the rejection. Dong et al teach that harpin did not overcome the SAR defect nor did it induce resistance to the pathogens *Peronospora parasitica* or *Pseudomonas syringae* pv tomato DC3000(pg 209, left column, paragraph 1, and paragraph spanning the columns on pg 210).

6. Claims 3-11, 12-21 and 75-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. All the rejections are new, due to amendment.

Claims 75-76 are indefinite in their recitation of "conditions effective to maximize the benefit of the value added trait" in lines 7 and 8, respectively. Such conditions are not described in the specification, and it is not clear what those conditions are.

Claim Rejections - 35 USC § 102

7. Claims 3-10 and 75-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Qiu et al (WO 98/24297). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 November 2002, as applied to claims 1-10. Applicant's arguments filed 9 April 2003 have been fully considered but they are not persuasive.

Applicant urges that Qui et al teaches imparting disease resistance to a plant or seed comprising a transgene encoding a hypersensitive response elicitor, while the instant claims state that the transgene does not encode a hypersensitive response elicitor (response pg 12).

This is not found persuasive because transgenic plants also comprise a transgene encoding a selectable marker gene. The instant claims state that the plants comprise a transgene that does not encode a hypersensitive response elicitor, but does not state that the plant is not transformed at all with a transgene encoding a hypersensitive response elicitor.

8. Claims 3-10 and 75-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogdanove et al (WO 99/07206). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 November 2002, as applied to claims 1-10. Applicant's arguments filed 9 April 2003 have been fully considered but they are not persuasive.

Applicant urges that Bogdanove et al teaches imparting disease resistance to a plant or seed comprising a transgene encoding a hypersensitive response elicitor, while the instant claims state that the transgene does not encode a hypersensitive response elicitor (response pg 12).

This is not found persuasive because transgenic plants also comprise a transgene encoding a selectable marker gene. The instant claims state that the plants comprise a transgene that does not encode a hypersensitive response elicitor, but does not state that the plant is not

transformed at all with a transgene encoding a hypersensitive response elicitor.

9. Claims 3-14, 17-18, 20-21 and 75-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al (1999, Plant Cell 11:223-235). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 November 2002, as applied to claims 1-14, 17-18 and 20-21. Applicant's arguments filed 9 April 2003 have been fully considered but they are not persuasive.

Applicant urges that *Phytophthora parasitica* var *nicotianea* does not produce the elicitin cryptogein or any other elicitin. Applicant does acknowledge that Keller teaches topical application of other *Phytophthora* species and $Harpin_{Pss}$ (response pg 13-14).

This is not found persuasive because other *Phytophthora* species do produce hypersensitive response elicitor proteins and $Harpin_{Pss}$ is one.

Applicant urges that the lack of resistance to *Erysiphe cichoracearum* and *Thielaviopsis bassicola* was present in both the transformed and wild-type plants; thus, the lack of resistance was not a function of the transgene (response pg 13).

This is not found persuasive. The transgene failed to provide resistance to those pathogens; thus, the transgene had a deleterious effect. Note that the specification doe not define or describe transgenes that have a value-added trait but also have a deleterious effect.

Applicant urges that the claims recite that the transgene does not encode a hypersensitive response elicitor protein; Keller et al does not teach topical application of a hypersensitive response elicitor protein to a plants transformed with e gene other than one that encodes a hypersensitive response elicitor protein (response pg 14).

This is not found persuasive. The claims language is open. The plants of the claimed

method comprise a transgene that does not encode a hypersensitive response elicitor protein. There is no statement that the plants cannot have more than one transgene, one of which encodes a hypersensitive response elicitor protein, and others that encode other traits.

Keller et al teach that the transformation method used a selection method; thus the vector encoded a selectable marker (pg 232, right column, paragraph 2. Additionally, the transformation vector also comprises an ampicillin resistance gene, as the vector upon which it was based is pBluescript (pg 232, left column, paragraph 3). Furthermore, Keller et al teach a method of applying *P. cryptogea* , which produces cryptogein, to plants transformed with a transgene that comprises the coding sequence for GUS operably linked to a plant defense promoter (pg 224, right column, paragraph 3 and Figure 1).

Claim Rejections - 35 USC § 103

10. Claims 3-11, 13-21 and 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Qiu et al and Bogdanove et al. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 November 2002, as applied to claims 1-21. Applicant's arguments filed 9 April 2003 have been fully considered but they are not persuasive.

Applicant urges that neither Qui et al nor Bogdanove et al teach imparting disease resistance to a plant or seed comprising a transgene encoding a hypersensitive response elicitor, wherein the transgene does not encode a hypersensitive response elicitor (response pg 12).

This is not found persuasive because transgenic plants also comprise a transgene encoding a selectable marker gene, as discussed above. The instant claims state that the plants comprise a transgene that does not encode a hypersensitive response elicitor, but do not state that

the plant is not transformed at all with a transgene encoding a hypersensitive response elicitor.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.
June 24, 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600